Appendix P
Colorado Medical Assistance Program
Prior Authorization Procedures and Criteria and Quantity Limits
For Physicians and Pharmacists

Drugs requiring a prior authorization are listed in this document. The Prior Authorization criteria are based on FDA approved indications, CMS approved compendia, and peer-reviewed medical literature.

Prior Authorization Request (PAR) Process

- Products qualify for a 3 day emergency supply in an emergency situation. In this case, call the help desk for an override.
- Pharmacy PA forms are available by visiting: https://www.colorado.gov/hcpf/pharmacy-resources
- PA forms can be signed by anyone who has authority under Colorado law to prescribe the medication. Assistants of authorized persons cannot sign the PA form
- Physicians or assistants who are acting as the agents of the physicians can request a PA by phone
- Pharmacists from long-term-care pharmacies and infusion pharmacy must obtain a signature from someone who is authorized to prescribe drugs before they submit PA forms
- Pharmacists from long-term-care pharmacies and infusion pharmacies can request a PA by phone if specified in the criteria
- All PA's are coded online into the PA system
- Prior Authorizations can be called or faxed to the helpdesk at

  Phone: 1-800-424-5725
  Fax: 1-888-424-5881

- Non-narcotic prescriptions may be refilled after 75% of previous fill is used. Narcotic prescriptions may be refilled after 85% of the previous fill is used. Synagis may be refilled after 92.5% of the previous fill is used.

Medical Supply Items and Medications

- All supplies, including insulin needles, food supplements and diabetic supplies are not covered under the pharmacy benefit, but are covered as medical supply items through Durable Medical Equipment (DME)
- If a medical benefit requires a PA, the PA request can be submitted through the provider application available at: http://www.coloradopar.com/
- DME questions should be directed to DXC Technology (Formerly Hewlett Packard Enterprise) 1-844-235-2387. Only policy questions regarding Durable Medical Equipment should be directed to the state at 303-866-3406.
- Medications given in a hospital, doctor's office or dialysis unit are to be billed directly by those facilities as a medical item. IV Fluids, meds, etc. may be billed by the pharmacy when given in a long-term care facility or by home infusion.
- Initiation of pharmaceutical product subject to Prior Authorization:
  - Please note that starting the requested drug, including a non-preferred drug, prior to a PA request being reviewed and approved, through either inpatient use, by using office "samples", or by any other means, does not necessitate Medicaid approval of the PA request.

Drug	Criteria	PAR Length
Drug classes that have been migrated to the Preferred Drug List (PDL) https://www.colorado.gov/hcpf/pharmacy-resources	Anticoagulants (oral), Antidepressants, Antiemetics, Antiherpetics, Antihistamines with decongestants, Antihypertensives, Antiplatelets, Atypical Antipsychotics (oral), Bisphosphonates (oral), Constipation (opioid-induced), Diabetes Management Classes, Erythropoiesis Stimulating Agents, Fibromyalgia Agents, Filgrastim/Pegfilgrastim/Sargromastim/Filgrastim-SNDZ, Fluoroquinolones, Growth Hormones, Hepatitis C Virus Treatments, Insulin, Intranasal Corticosteroids, Leukotrienes, Multiple Sclerosis Agents, Neurocognitive Disorder Agents, Ophthalmic Allergy Products, Otezla (apremilast), Overactive Bladder Agents, Pancreatic Enzymes, Proton Pump Inhibitors, Pulmonary Arterial Hypertension Therapies, Respiratory Inhalents, Sedative Hypnotics, Skeletal Muscle Relaxants, Stimulants and other ADHD Agents, Targeted Immune Modulators (self-administered), Testosterone Products, Topical Immunomodulators, Triptans	
ACETAMINOPHEN CONTAINING PRODUCTS	A prior authorization is required for dosages of acetaminophen containing products over 4000mg/day of acetaminophen. Doses over 4000mg/day are not qualified for emergency 3 day supply PA	N/A
AIMOVIG (erenumab-aooe) *Effective 06/15/18*	**Aimovig®** (erenumab-aooe) will be approved if the following criteria are met: • Prescribed for an adult member for prevention of episodic or chronic migraine AND • Member has diagnosis of migraine with or without aura AND • Member has tried and failed 2 oral preventative pharmacological agents with established efficacy for migraine prevention (i.e. divalproex, topiramate, metoprolol, propranolol, etc. [Level A per American Headache Society/American Academy of Neurology]). Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction AND If prescribed for **episodic migraine**: • Member has history of 4-14 migraine days per month AND • Member is not prescribed this medication for medication overuse headache AND • Member does not have history of MI, stroke, TIA, unstable angina, coronary artery bypass surgery, or other revascularization procedures within previous 12 months AND • Initial authorization will be for 6 months. Continuation (12 month authorization) will require documentation of clinically significant improvement after 4 months use (and documentation of number of migraine days per month) If prescribed for **chronic migraine**: • Member has history of 15 or more headache days per month where 8 or more were migraine days for three or more months AND • Member is not prescribed this medication for medication overuse headache AND • Member is not concurrently taking another migraine preventative medication AND • Member does not have history of MI, stroke, TIA, unstable angina, coronary artery bypass surgery, or other revascularization procedures within previous 12 months AND • Initial authorization will be for 4 months. Continuation (12 month authorization) will require documentation of clinically significant improvement after 3 months use (and documentation of number of migraine days per month)	See criteria

	Aimovig maximum dose is 140mg monthly	

ALBUMIN	Must have an FDA approved indication and given in the member's home or in a long-term care facility for approval. The following are FDA approved indications:
	• Hypoproteinemia
	• Burns
	• Shock due to:
	  o Burns
	  o Trauma
	  o Surgery
	  o Infection
	• Erythrocyte resuspension
	• Acute nephrosis
	• Renal dialysis
	• Hyperbilirubinemia
	• Erythroblastosis fetalis
		One year

ALLERGY EXTRACT PRODUCTS (Oral) Grastek, Oralair, Ragwitek	***Grastek (Timothy grass pollen allergen extract)*** Must be between 5 and 65 years old. Must not be pregnant or nursing. Must be prescribed by an allergist. Must have a documented diagnosis to ONLY timothy grass pollen allergen extract or the Pooideae family (meadow fescue, orchard, perennial rye, Kentucky blue, and red top grasses) confirmed by positive skin test or IgE antibodies. Must have tried and failed allergy shots for reasons other than needle phobia. Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Must be willing to administer epinephrine in case of severe allergic reaction. Must take first dose in physician's office. Must be started 12 weeks prior to the season if giving only seasonally. May be taken daily for up to 3 consecutive years. Must NOT have: • Severe, unstable or uncontrolled asthma • Had an allergic reaction in the past that included trouble breathing, dizziness or fainting, rapid or weak heartbeat • Ever had difficulty with breathing due to swelling of the throat or upper airway after using any sublingual immunotherapy before • Been diagnosed with eosinophilic esophagitis • Allergic to any of the inactive ingredients contained in Grastek which include gelatin, mannitol, and sodium hydroxide • A medical condition that may reduce the ability to survive a serious allergic reaction including but not limited to: markedly compromised lung function, unstable angina, recent myocardial infarction, significant arrhythmia, and uncontrolled hypertension. • Taking medications that can potentiate or inhibit the effect of epinephrine including but not limited to: beta-adrenergic blockers, alpha-adrenergic blockers, ergot alkaloids, tricyclic antidepressants, levothyroxine, monoamine oxidase inhibitors, certain antihistamines, cardiac glycosides, and diuretics. • Be taken with other immunotherapy (oral or injectable) ***Oralair (Sweet Vernal, Orchard, Perennial Rye, Timothy, Kentucky Blue Grass mixed pollens allergen extract)***	One year

	Must be between 10 and 65 years old. Must not be pregnant or nursing. Must be prescribed by an allergist. Must have a documented diagnosis to ONLY Sweet Vernal, Orchard, Perennial Rye, Timothy, or Kentucky Blue Grass allergen extract confirmed by positive skin test or IgE antibodies. Must have tried and failed allergy shots for reasons other than needle phobia. Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Must be willing to administer epinephrine in case of severe allergic reaction. Must take first dose in physician's office. Must NOT have: • Severe, unstable or uncontrolled asthma • Had an allergic reaction in the past that included trouble breathing, dizziness or fainting, rapid or weak heartbeat • Ever had difficulty with breathing due to swelling of the throat or upper airway after using any sublingual immunotherapy before • Been diagnosed with eosinophilic esophagitis • Allergic to any of the inactive ingredients contained in Oralair which include mannitol, microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate, and lactose monohydrate. • A medical condition that may reduce the ability to survive a serious allergic reaction including but not limited to: markedly compromised lung function, unstable angina, recent myocardial infarction, significant arrhythmia, and uncontrolled hypertension. • Taking medications that can potentiate or inhibit the effect of epinephrine including but not limited to: beta-adrenergic blockers, alpha-adrenergic blockers, ergot alkaloids, tricyclic antidepressants, levothyroxine, monoamine oxidase inhibitors, certain antihistamines, cardiac glycosides, and diuretics. • Be taken with other immunotherapy (oral or injectable) ***Ragwitek (short ragweed pollen allergen extract)*** Must be between 18 and 65 years old. Must be started 12 weeks prior to the season and only prescribed seasonally. Must not be pregnant or nursing. Must be prescribed by an allergist. Must have a documented diagnosis to ONLY short ragweed pollen allergen extract or the Ambrosia family (giant, false, and western ragweed) confirmed by positive skin test or IgE antibodies. Must have tried and failed allergy shots for reasons other than needle phobia. Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Must be willing to administer epinephrine in case of a severe allergic reaction. Must take first dose in physician's office. Must NOT have: • Severe, unstable or uncontrolled asthma • Had an allergic reaction in the past that included trouble breathing, dizziness or fainting, rapid or weak heartbeat • Ever had difficulty with breathing due to swelling of the throat or upper airway after using any sublingual immunotherapy before • Been diagnosed with eosinophilic esophagitis	

	• Allergic to any of the inactive ingredients contained in Ragwitek which include gelatin, mannitol, and sodium hydroxide • A medical condition that may reduce the ability to survive a serious allergic reaction including but not limited to: markedly compromised lung function, unstable angina, recent myocardial infarction, significant arrhythmia, and uncontrolled hypertension. • Taking medications that can potentiate or inhibit the effect of epinephrine including but not limited to: beta-adrenergic blockers, alpha-adrenergic blockers, ergot alkaloids, tricyclic antidepressants, levothyroxine, monoamine oxidase inhibitors, certain antihistamines, cardiac glycosides, and diuretics. • Be taken with other immunotherapy (oral or injectable)	
ALPHA –1 PROTEINASE INHIBITORS Aralast, Prolastin, Zemaira	FDA approved indication if given in the member's home or in a long-term care facility: • **Aralast®**: Chronic augmentation therapy in members having congenital deficiency of Alpha –1 Proteinase Inhibitor with clinically evident emphysema • **Prolastin®**: Emphysema associated with Alpha-1 Antitrypsin Deficiency • **Zemaira®**: Chronic augmentation and maintenance therapy in members with Alpha- 1 Proteinase Inhibitor deficiency with clinically evident emphysema	Lifetime
ANOREXIANTS	Weight loss medications are not a covered benefit. Adipex P (phentermine) Belviq (lorcaserin) Contrave (naltrexone/bupropion) Lomaira (phentermine) Qsymia (phentermine/topiramate ER) Phentermine Saxenda (liraglutide) Xenical (Orlistat)	Weight loss drugs are not a covered benefit.
ANTI-ANEMIA DRUGS (Injectable)	Injectable anti-anemia agents (i.e. Infed, Ferrlecit, Venofer, etc.) will be approved for members meeting the following criteria: • Medication has FDA-approved indication for treating iron deficient anemia AND • Oral preparations are ineffective or cannot be used AND • Medication is being administered in a long-term care facility or in the member's home by a home healthcare provider	Lifetime
ATYPICAL ANTIPSYCHOTICS (Injectable formulations) Abilify Maintena, Aristada, Geodon injection, Invega Sustenna, Invega Trinza, Risperdal Consta, Zyprexa Relprevv	A prior authorization will only be approved as a pharmacy benefit when the medication is administered in a long-term care facility or in a member's home by a home healthcare provider. Oral atypical antipsychotic criteria can be found on the Preferred Drug List.	One year
BACTROBAN (mupirocin) Cream and Nasal Ointment	**Bactroban Cream** (mupirocin calcium cream) must be prescribed for the treatment of secondarily infected traumatic skin lesions (up to 10 cm in length or 100 cm^2 in total area), impetigo, infected eczema or folliculitis caused by susceptible strains of Staphylococcus aureus and Streptococcus pyogenes. **Bactroban Nasal Ointment** (mupirocin calcium) must be prescribed for the eradication of nasal colonization with methicillin-resistant Staphylococcus aureus in adult patients and health care workers as part of a comprehensive infection control program to reduce the risk of infection among patients at high risk of methicillin-resistant S. aureus infection during institutional outbreaks of infections with this pathogen.	Cream: One year Nasal Ointment: Lifetime

BARBITURATES	Barbiturates including phenobarbital will receive prior authorization approval for use in epilepsy, cancer, chronic mental health disorder, sedation, treatment of insomnia, tension headache, muscle contraction headache and treatment of raised intracranial pressure. All other uses will require manual review. **Phenobarbital** will be approved for neonatal narcotic abstinence syndrome based on the following criteria: • The member has a diagnosis of non-opiate or polysubstance abuse OR • The member has first failed methadone for the diagnosis of opiate withdrawal AND • Serum phenobarbital levels are being monitored. • Max 3 month approval for neonatal narcotic abstinence syndrome **Butalbital Containing Products:** • Effective August 1, 2014, products containing butalbital are limited to 180 units in 30 days. For members receiving more than 180 tablets in 30 days, these claims will be escalated to the Department for individual review. Please note that if more than one agent is used, the combined total utilization may not exceed 180 units in 30 days. • Coverage criteria for butalbital with codeine containing products can be found on the PDL <u>Dual-eligible Medicare-Medicaid Beneficiaries:</u> Beginning on January 1, 2013 Colorado Medicaid will no longer cover barbiturates for Medicare-Medicaid enrollees (dual-eligible members). For Medicaid primary members, barbiturates will be approved for use in epilepsy, cancer, chronic mental health disorder, sedation, treatment of insomnia, tension headache, muscle contraction headache and treatment of raised intracranial pressure. All other uses will require manual review.	One year (3 months for neonatal narcotic abstinence syndrome)
BENLYSTA (belimumab)	**Benlysta®** prior authorization may be approved only when documentation has been received indicating that the drug is being administered in the member's home or long-term care facility. The member must also meet the following criteria: • Diagnosis of autoantibody positive SLE with organ involvement; AND • Incomplete response to standard therapy from at least two of the following therapeutic classes: antimalarials, immunosuppressants and glucocorticoids; AND • Maintenance of standard therapy while on BENLYSTA.	One year
BENZODIAZEPINES Dual-eligible Medicare-Medicaid Beneficiaries	<u>Dual-eligible Medicare-Medicaid Beneficiaries:</u> Benzodiazepines will no longer be a Medicaid benefit for Medicare-Medicaid enrollees (dual-eligible members). The claims are no longer excluded from Medicare part D coverage and therefore must be billed to Medicare part D. Colorado Medicaid will no longer cover these medications for these members beginning on January 1, 2013.	One year
BONE RESORPTION SUPPRESSION AND RELATED AGENTS (Injectable formulations) Boniva, Aredia, Miacalcin, Zemplar, Hectorol, Zometa, Reclast, Pamidronate, Ganite	A prior authorization will only be approved as a pharmacy benefit when the medication is administered in a long-term care facility or in a member's home. Prolia (denosumab) will be approved if the member Meets the following criteria: • Member is in a long term care facility or home health (this medication is required to be administered by a healthcare professional) AND • Member has one of the following diagnoses: o Postmenopausal osteoporosis with high fracture risk o Osteoporosis o Bone loss in men receiving androgen deprivation therapy in prostate cancer	One year

	○ Bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer AND • Member has serum calcium greater than 8.5mg/dL AND • Member is taking calcium 1000 mg daily and at least 400 IU vitamin D daily AND • Has trial and failure of preferred bisphosphonate for one year AND (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) • Member meets ANY of the following criteria: ○ has a history of an osteoporotic vertebral or hip fracture ○ has a pre-treatment T-score of < -2.5 ○ has a pre-treatment T-score of < -1 but > -2.5 AND either of the following: • Pre-treatment FRAX score of > 20% for any major fracture • Pre-treatment FRAX score of > 3% for hip fracture Maximum dose of Prolia is 60mg every 6 months	
BLOOD PRODUCTS	FDA approved indications if given in the member's home or in a long-term care facility: • Plasma protein fraction; shock due to burns, trauma, surgery; hypoproteinemia; adult respiratory distress syndrome; cardiopulmonary bypass; liver failure; renal dialysis; or hemophilia.	Lifetime
BOTULINUM TOXIN Botox, Dysport, Myobloc, Xeomin	If given in the member's home or in a long-term care facility. • *Cervical or Facial Dystonia* ***Not approved for Cosmetic Purposes***	One year
BOWEL PREPERATION AGENTS	For the following Bowel Preparation Agents, members will require a prior authorization for quantities greater than 2 units per month. • Colyte • Gavilyte-C • Gavilyte-H • Gavilyte-N • Gialax • Golytely • Moviprep • Peg-Prep • Suprep • Trilyte	30 days
BRAND NAME MEDICATIONS and GENERIC MANDATE	<u>Brand Name Medications and Generic Mandate:</u> • Brand name drug products that have a therapeutically equivalent generic drug product (as determined by the FDA) will require prior authorization for brand product coverage and will be covered without a prior authorization if meeting one of the following exceptions: ○ The brand name drug is prescribed for the treatment of: ▪ Biologically based mental illness defined in 10-16-104 (5.5) C.R.S. ▪ Cancer ▪ Epilepsy ▪ HIV/AIDS ○ The Department has determined that the brand name product is lower cost than the therapeutically equivalent generic • Prior authorization for use of a brand name drug product that has a therapeutically equivalent generic (and does not meet exceptions above) may also be approved if:	One year

	○ The prescriber is of the opinion that a transition to the generic equivalent of the brand name drug would be unacceptably disruptive to the patient's stabilized drug regimen ○ The patient is started on the generic equivalent drug but is unable to continue treatment on the generic drug as determined by the prescriber	
CERDELGA (eligulstat)	**Cerdelga®** will be approved if all the following criteria are met: • Member has a diagnosis of Gaucher disease type 1 **AND** • Documentation has been provided to the Department that the member is a CYP2D6 extensive, intermediate, or poor metabolizer as detected by an FDA cleared test **AND** • Members who are CYP2D6 intermediate or poor metabolizers are not taking a strong CYP3A inhibitor (e.g, indinavir, nelfinavir, ritonavir, saquinavir, suboxone, erythromycin, clarithromycin, telithromycin, posaconazole, itraconazole, ketoconazole, nefazodone) **AND** • Members who are CYP2D6 extensive or intermediate metabolizers are not receiving strong or moderate CYP2D6 inhibitors (e.g, sertraline, duloxetine, quinidine, paroxetine, fluoxetine, buproprion, terbinafine) **AND** a strong or moderate CYP3A inhibitor (e.g, indinavir, nelfinavir, ritonavir, saquinavir, suboxone, erythromycin, clarithromycin, telithromycin, posaconazole, itraconazole, ketoconazole, fluconazole, nefazodone, verapamil, diltiazem) Quantity Limits: Max 60 tablets/30 days	One year
CHOLBAM (cholic Acid)	**Cholbam®** capsules will be approved for members who meet the following criteria: • Bile acid synthesis disorders: ○ Member must be greater than 3 weeks old in age AND ○ Member has a diagnosis for bile acid synthesis disorder due to single enzyme defect (Single Enzyme-Defect Disorders: Defective sterol nucleus synthesis, 3β-hydroxy-Δ-c27-steroid oxidoreductase deficiency, AKR1D1 deficiency, CYP7A1 deficiency, Defective side-chain synthesis, CYP27A1 deficiency (cerebrotendinous xanthomatosis), 2-methylacyl-CoA racemase deficiency (AMACR), 25-hydroxylation pathway (Smith–Lemli-Opitz). • Peroxisomal disorder including Zellweger spectrum disorders: ○ Member must be greater than 3 weeks old in age AND ○ Member has diagnosis of peroxisomal disorders (PDs) including Zellweger spectrum disorders AND ○ Member has manifestations of liver disease, steatorrhea or complications from decreased fat soluble vitamin absorption.	One year
CIALIS (tadalafil)	**Cialis®** will be approved for members with a documented diagnosis of BPH who have failed a trial of finasteride (at least 3 months in duration) AND either a trial of a nonselective alpha blocker (therapeutic dose for at least two months) OR a trial of tamsulosin (therapeutic dose for at least one month). Documentation of BPH diagnosis will require BOTH of the following: • AUA Prostate Symptom Score ≥ 8 AND • Results of a digital rectal exam. Cialis will not be approved for any patient continuing alpha-blocker therapy as this combination is contraindicated in this population. Doses exceeding 5mg per day of Cialis® will not be approved.	One year
COLCRYS (colchicine)	Quantity Limits: • Chronic hyperuricemia/gout prophylaxis: 60 tablets per 30 days • Familial Mediterranean Fever:120 tablets per 30 days	One year
COUGH AND COLD (Rx products)	Member <21 years: covered benefit. A prior authorization is not needed.	One year

	Member ≥ 21 years must have diagnosis of a chronic condition such as COPD or asthma.	
DALIRESP (roflumilast)	**Daliresp®** tablets will be approved for members that meet the following criteria: • Member has a diagnosis for severe COPD with history of COPD exacerbations (2 or more per year) and chronic bronchitis AND • Member must be greater than 18 years of age AND • Member must have failed a trial of two of the following: long-acting beta2 agonist, preferred anticholinergic/anticholinergic combination, or preferred inhaled anticholinergic/anticholinergic combinations due to lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction AND • Member must not have moderate to severe liver disease (Child Pugh B or C). Note: this medication is not a bronchodilator and cannot be used for acute bronchospasms	One year
DARAPRIM (pyrimethamine)	**Daraprim®** will be approved if all the following criteria are met: • Member is being treated for toxoplasmic encephalitis or congenital toxoplasmosis or receiving prophylaxis for congenital toxoplasmosis AND • Daraprim is prescribed in conjunction with an infectious disease specialist AND • Member does not have megaloblastic anemia due to folate deficiency AND • For prophylaxis, member has experienced intolerance to prior treatment with trimethoprim-sulfamethoxazole (TMP-SMX) meeting one of the following: o Member has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and is still unable to tolerate o Member has evidence of life threatening-reaction to trimethoprim-sulfamethoxazole (TMP-SMX) in the past (e.g. toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome) OR • Member is being treated for acute malaria due to susceptible strains of plasmodia AND • Member has tried and had an inadequate response or intolerant to two other malaria treatment regimens (such as but not limited to atovaquone/proguanil, Coartem, chloroquine, hydroxychloroquine, chloroquine plus Primaquine, quinine plus clindamycin, quinidine plus doxycycline) AND • Daraprim is prescribed in conjunction with an infectious disease specialist with travel/tropical medicine expertise AND • Member does not have megaloblastic anemia due to folate deficiency Note: The Center for Disease Control does not recommend Daraprim for the prevention or the treatment of malaria	8 weeks
DESI DRUGS	DESI drugs (Drugs designated by the Food and Drug Administration as Less Than Effective Drug Efficacy Study Implementation medications) are not a covered benefit.	None
DIFICID (fidoxomicin)	**Dificid®** will be approved if all the following criteria are met: • The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient's medical records AND • Prescriber must be a gastroenterologist or an infectious disease specialist AND • Diagnosed with Clostridium difficile-associated diarrhea AND • ≥ 18years of age AND • Failed at least a 10 day treatment course with oral metronidazole AND oral vancomycin OR • Allergy and/or intolerance to both metronidazole and vancomycin Quantity limits:	10 days

	Dificid: Max 20 tabs/30 days	
DUPIXENT (dupilumab)	**Dupixent®** will be approved if all the following criteria have been met: • Member is 18 years and older AND • Member has a diagnosis of severe chronic atopic dermatitis AND • Member has a history of failure, contraindication, or intolerance to both of the following: o One medium potency to very-high potency topical corticosteroid [e.g.,Elocon (mometasone furoate), Synalar (fluocinolone acetonide), Lidex (fluocinonide)] AND o One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)] AND • For members under 18 years of age, must be prescribed by or in conjunction with a dermatologist • Quantity limit of 2 syringes every 28 days after initial 14 days of therapy (first dose is twice the regular scheduled dose)	One Year
EGRIFTA (tesamorelin acetate)	**Egrifta®** will be approved if all the following is met: • Must be prescribed in consultation with a physician who specializes in HIV/AIDS AND • Member is 18 years of age or older AND • Member has a diagnosis of HIV-related lipodystrophy with excess abdominal fat meeting the following criteria: o Male member must have a waist circumference of at least 95cm (37.4in) and a waist to hip ratio of at least 0.94 OR o Female member must have a waist circumference of at least 94cm (37in) and a waist to hip ratio of at least 0.88 AND o Baseline waist circumference and waist to hip ratio must be provided • Member is currently receiving highly active antiretroviral therapy including protease inhibitors, nucleoside reverse transcriptase inhibitor, or non-nucleoside reverse transcriptase inhibitors AND • Member does not have a diagnosis of hypophysectomy, hypopituitarism, pituitary surgery, head irradiation or head trauma AND • Member does not have any active malignancy or history of malignancy AND • For women of childbearing potential, member must have a negative pregnancy test within one month of therapy initiation	6 months
ELESTRIN GEL (estradiol)	A prior authorization will only be approved if a member has tried and failed on generic oral estradiol therapy and diagnosed with moderate-to-severe vasomotor symptoms (hot flashes) associated with menopause. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)	One year
EMFLAZA (deflazacort)	**Emflaza®** may be approved if all the following criteria are met: • Member is at least 5 years of age or older AND • Member has diagnosis of Duchenne muscular dystrophy and a documented mutation in the dystrophin gene AND • Member must have documented (per claims history or provider notes) adequate trial and/or failure to prednisone therapy, adequate trial duration is at least three month. (Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions) AND • The medication is prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy and/or neuromuscular disorders. AND • Serum creatinine kinase activity at least 10 times the upper limit of normal at some stage in their illness AND • Absence of active infection including tuberculosis and hepatitis B virus	One year

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- Maximum dose of 0.9mg/kg daily for tablets and suspension, may be rounded up to nearest ml

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<tr><td>EMVERM (mebendazole)</td><td>

Emverm® will be approved for members that meet the following criteria:

- Member is 2 years or older AND
- Member has a diagnosis of one of the following: Ancylostoma duodenale or Necator americanus (hookworm), Ascariasis (roundworm), Enterobiasis (pinworm), or Trichuriasis (whipworm) AND
- Member has failed a trial of albendazole for FDA approved indication and duration (Table 1) (Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) AND
- For diagnoses other than pinworm, Emverm is being prescribed by an infectious disease specialist AND
- Female members have a negative pregnancy test AND
- Emverm® Is being prescribed in accordance to FDA dosing and duration (Table 1)

Quantity limits: Based on indication (Table 1)

Table 1: Emverm FDA Approved Dosing and Duration in Adults and Children

Diagnosis	Dose	Duration	Quantity Limits
Ancylostoma duodenale or Necator americanus (hookworm)	100 mg twice daily	3 consecutive days, may be repeated in 3 weeks in needed.	6 tablets/member
Ascariasis (roundworm)	100 mg twice daily	3 consecutive days, may be repeated in 3 weeks if needed.	6 tablets/member
Enterobiasis (pinworm)	100 mg once	May give second dose in three weeks if needed.	2 tablets/member
Trichuriasis (whipworm)	100 mg twice daily	3 consecutive days, may be repeated in 3 weeks in needed.	6 tablets/member

</td><td>See Table</td></tr>
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ENTRESTO (sacubitril/valsartan)	**Entresto®** will be approved for members if the following criteria has been met: • Member has a diagnosis of heart failure with reduced ejection fraction and NYHA Class II to IV AND • Member is NOT currently on ACE-inhibitor or Angiotensin Receptor Blocking agent AND • Member does not have history of angioedema related to previous ACE inhibitor or ARB therapy	One year
ERECTILE DYSFUNCTION OR SEXUAL DYSFUNCTION PRODUCTS Caverject, Cialis, Edex, Imvexxy, Levitra, Muse, Viagra, Addyi, Osphena, Premarin Cream, Sildenafil, Staxyn, Stendra, Xiaflex, Yohimbine	These drugs are not a covered benefit for SD/ED indications. Yohimbine: PAs can no longer be approved for erectile dysfunction. Any PAs for use as a mydriatic agent or a vasodilator (not related to erectile dysfunction) may be approved.	Not available Not qualified for emergency 3 day supply
ESBRIET (Pirenidone)	**Esbriet®** will be approved if all the following criteria are met: • Member has been diagnosed with idiopathic pulmonary fibrosis AND • Is being prescribed by or in conjunction with a pulmonologist AND • Member is 18 years or older AND • Member has baseline ALT, AST, and bilirubin prior to starting therapy AND • Member does not have severe (Child Pugh C) hepatic impairment, severe renal impairment (Crcl<30 ml/min), or end stage renal disease requiring dialysis AND • Female members of reproductive potential must have been counseled regarding risk to the fetus AND • Member is not receiving a strong CYP1A2 inducer (e.g, carbamazepine, phenytoin, rifampin)	One year
EUCRISA (crisaborole)	**Eucrisa®** will be approved if all the following criteria are met: • Member is at least 2 years of age and older AND • Member has a diagnosis of mild to moderate atopic dermatitis AND • Member has a history of failure, contraindication, or intolerance to at least two medium- to high-potency topical corticosteroid for a minimum of 2 weeks, or is not a candidate for topical corticosteroids AND • Member must have trialed and/or failed pimecrolimus and tacrolimus. Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions. AND • Must be prescribed by or in conjunction with a dermatologist	One year
EXJADE (deferasirox)	Please see "Jadenu and Exjade"	
FERRIPROX (Deferiprone)	**Ferriprox®** will be approved if all the following is met: • Must be prescribed in conjunction with a hematologist or oncologist AND • Member's weight must be provided AND • Member has a diagnosis of transfusion-related iron overload due to thalassemia syndrome or sickle cell disease AND • Member has an absolute neutrophil count > 1.5 x 109 AND • Member has failed or has had an inadequate response to Desferal (deferoxamine) AND Exjade (deferasirox) as defined by serum ferritin >2,500mcg/L before treatment with Ferriprox OR member has been intolerant to or experienced clinically significant adverse effects to Desferal	One year

	(deferoxamine) or Exjade (deferasirox) such as evidence of cardiac iron overload or iron-induced cardiac dysfunction. Maximum dose of Ferriprox® is 99mg/kg/day	
FLUORIDE PRODUCTS	Prescription fluoride products: • Prescription fluoride products will be approved for members less than 21 years of age without a prior authorization. • For members 21 years of age or older approval will be granted if using well water or living in an under-fluoridated area designated by the CDC*. • Approval for members not meeting these criteria will require a letter of necessity and will be individually reviewed. OTC fluoride products: • The following OTC fluoride products are eligible for prior authorization approval for all members using well water or living in an under-fluoridated area designated by the CDC*: fluoride chewable tablets, ludent fluoride chewable tablets, sodium fluoride 0.5mg/mL drops • Approval for members not meeting these criteria will require a letter of necessity and will be individually reviewed. *Information and reports regarding water fluoridation can be found on the CDC website at: https://nccd.cdc.gov/DOH_MWF/Default/CountyList.aspx?state=Coloradateid=8&stateabbr=CO&reportLevel=2.	One year
FUZEON (enfuvirtide)	If administered in the physician's office or delivered to physician's office, physician must bill as a medical claim on the 1500 claim form **(no PA required).** If administered in the member's home or in a long-term care facility, a prior authorization is required and must meet the criteria below for approval Based on clinical trial data, ENF should be used as part of an *optimized* background regimen for treatment-experienced members: • For treatment-experienced members with evidence of HIV-1 replication, treatment should include at least one antiretroviral agent with demonstrated HIV-1 susceptibility on the basis of genotypic/phenotypic *resistance* assays, and *two* "active" antiretroviral agents. o Members must have limited treatment options among currently commercially available agents. • Members must be 18 years of age or older with advanced HIV-1 infection, and not responding to approved antiretroviral therapy. • Members must have a CD4 lymphocyte count less than 100 cells/mm3 and a viral load greater than 10,000 copies/ml (measurement within the last 90 days). Past adherence must be demonstrated based on: • Attendance at scheduled appointments, and/or • Prior antiretroviral regimen adherence, and/or • Utilization data from pharmacy showing member's use of medications as prescribed • Ability to reconstitute and self-administer ENF therapy. At 24 weeks, members must experience at least ≥ 1 $\log_{10}$ decrease in HIV RNA or have HIV RNA below quantifiable limits to continue treatment with ENF. Members are not eligible if antiretroviral treatment-naive and/or infected with HIV-2.	Six months

	Pre-approval is necessary Practitioner must either be Board Certified in Infectious Disease, or be an HIV experienced practitioner. Verification must be produced with the prior approval documents. **These guidelines may be modified on the basis of other payer formularies and/or the emergence of new data.**	
GATTEX (teduglutide)	**Gattex®** will be approved if all of the following criteria are met: • Member is 18 years of age or older AND • Member has documented short bowel syndrome AND • Member is dependent on parenteral nutrition for twelve consecutive months AND • The prescribing physician is a gastroenterologist AND • Medical necessity documentation has been received and approved by Colorado Medicaid clinical staff (please fax to 303-866-3590 attn: Clinical Pharmacy Staff) • The initial prior authorization will be limited to a two month supply.	Two months initially; may be approved by State for up to one year
H2 BLOCKERS	Prescription H2 Blockers (generic products) do not require a prior authorization except for ranitidine capsules and liquid. Ranitidine capsules: Require the prescribing provider to certify that capsules are medically necessary and that the member cannot use the tablets. Ranitidine liquid: A prior authorization will be approved for members with a feeding tube or who have difficulty swallowing. A prior authorization is not required for children under 12 years of age.	One year
HETLIOZ (tasimelteon)	**Hetlioz®** will be approved for members who meet the following criteria: • Have a documented diagnosis of non-24-hour sleep wake disorder (non-24 or N24) by a sleep specialist AND • Member is completely blind	One year
Homozygous Familial Hypercholesterolemia (HoFH)	**Juxtapid® (lomitapide)** Prior authorization will be approved if all of the following criteria are met: • Member is 18 years of age or older; • Member has documented diagnosis of homozygous familial hypercholesterolemia (HoFH); • Member has failed therapy with high dose statin therapy (e.g. atorvastatin 40mg or higher, Crestor 20mg or higher) • The prescribing physician is enrolled in the Juxtapid REMS program. **Kynamro® (mipomersen)** will be approved for members meeting all of the following criteria: • Confirmed diagnosis of homozygous familial hypercholesterolemia (HoFH) as determined by either a or b a. Laboratory tests confirming diagnosis of HoFH: LDLR DNA Sequence Analysis OR LDLR Deletion/Duplication Analysis for large gene rearrangement testing---only if the Sequence Analysis is negative OR APOB and dPCSK9 testing if both of the above tests are negative but a strong clinical picture exists. b. Documentation is received confirming a clinical or laboratory diagnosis of HoFH • Has a history of therapeutic failure, contraindication, or intolerance to high dose statin therapy or cholesterol absorption inhibitor (ezetimibe or bile acid resin) AND	One year

	• Is being prescribed by a physician specializing in metabolic lipid disorders AND • The prescriber is enrolled in the REMS program AND • Is not being used as monotherapy AND • Has baseline liver function (AST, ALT, ALK, and total bilirubin) AND • Does not have moderate or severe hepatic impairment or active liver disease.	
HORIZANT (gabapentil enacarbil)	**Horizant®** will be approved for members who have a diagnosis of Restless Leg Syndrome and who meet the following criteria: • Member has failed a one month trial of Mirapex® (pramipexole) and Requip® (ropinorole) AND • Member has had a positive therapeutic response to generic gabapentin but incomplete response due to duration of action. Max quantity: 30 tablets/30 days **Horizant®** will be approved for members who have a diagnosis of Post Herpetic Neuralgia and who meet the following criteria: • Member has failed a one month trial of tricyclic antidepressant, pregabalin and gabapentin Max quantity: 60 tablets / 30 days	One year
HORMONE THERAPY	**Depo Provera (medroxyprogesterone)/ Lunelle (estradiol cipionate/ medroxyprogesterone)** FDA approved indication if given in a long-term care facility or in the members home: • Females: Contraception, uterine bleeding, amenorrhea, endometrial cancer • Males: Sexual aggression / Pedophilia – Only Depo-Provera will be approved • Not approved for administration in the physician's office – these must be billed through medical. **Implanon (etonogestrel)** See PHYSICIAN ADMINISTERED DRUGS. Not a covered pharmacy benefit when implanted in the clinic or hospital outpatient center. **Nexplanon (etonogestrel)** • See PHYSICIAN ADMINISTERED DRUGS. Not a covered pharmacy benefit when implanted in the clinic or hospital outpatient center.	One year
HP ACTHAR (corticotropin)	**HP Acthar®** will be approved for members that meet the following criteria: • Member has a diagnosis of Infantile Spasms (West Syndrome) and meets all the criteria below: o Member is < 2 years of age o Member has electroencephalogram documenting diagnosis o Acthar is being used as monotherapy o Member does not have suspected congenital infection o Prescribed by or in consultation with a neurologist or epileptologist AND • Member does not have concomitant primary adrenocortical insufficiency or adrenocortical hyperfunction AND • Member is not receiving concomitant live or live attenuated vaccines AND • Member does not have one of the following concomitant diagnoses: o Scleroderma, osteoporosis, systemic fungal infections, ocular, herpes simplex, recent surgery, history of or the presence of a peptic ulcer, heart failure, uncontrolled hypertension, or sensitivity to proteins of porcine origin. AND • HP Acthar will be approved based on the following FDA recommended doses. (see Table 1)	4 week supply

	Table 1. FDA Recommended Dosing for HP Acthar **Diagnosis** / **Dose** Infantile Spasms under Age of 2 years: 75 units/m^2 IM twice daily for two weeks; After two weeks, dose should be tapered according to the following schedule: 30 U/m^2 IM in the morning for 3 days; 15 units/m^2 IM in the morning for 3 days; 10 units/m^2 IM in the morning for 3 days; and 10 units/m^2 IM every other morning for 6 days (3 doses). Quantity Limits: 4 week supply	

HUNTINGTONS CHOREA / TARDIVE DYSKINESIA AGENTS
Austedo, Ingrezza, Tetrabenazine
	Austedo® (deutetrabenazine) will be approved if all the following criteria have been met:
	• Member is 18 years and older with chorea secondary to Huntington's Disease OR Tardive Dyskinesia AND
	  o For chorea secondary to Huntington's Disease: member must have trialed and/or failed tetrabenazine, adequate trial duration is 1 month (Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions) OR
	  o For tardive dyskinesia a baseline AIMS AND 12 week AIMS are required. If the 12 week AIMS does not show improvement from baseline, the prior authorization will no longer be approved
	• Member does not have untreated depression, suicidal thoughts, or a history of suicide attempt AND
	• Member has been informed of the risks of depression and suicidality AND
	• Member does not have severe hepatic impairment
	
	• Maximum dose 48mg/day, 120 tablets per month
	
	Tetrabenazine will be approved if all the following criteria have been met:
	• Member is 18 years and older with chorea secondary to Huntington's Disease AND
	• Member does not have a history of suicide or untreated depression AND
	• Member has been informed of the risks of depression and suicidality AND
	• Member does not have severe hepatic impairment
	
	• Maximum dose 50mg/day, 60 tablets per month
	
	Ingrezza® (valbenazine) will be approved if all the following criteria have been met:
	• Member is 18 years or older AND
	• Member has been diagnosed with tardive dyskinesia clinically AND
	• Has a baseline Abnormal Involuntary Movement Scale (AIMS) AND
	• If there is no improvement at 6 weeks of therapy per AIMS, the medication will be discontinued
	
	• Quantity limit of 60 capsules per 30 days
		One year unless AIMS follow-up required

IVIG	Members must have one of the following conditions: • <u>Immunodeficiency disorders:</u>	One year

	○ Common Variable Immunodeficiency (CVID) ○ Severe Combined Immunodeficiency (SCID) ○ X-Linked Agammaglobulinemia ○ X-Linked with Hyperimmunoglobulin M (IgM) Immunodeficiency ○ Wiskott-Aldrich Syndrome ○ Pediatric Human Immunodeficiency Virus (HIV): ▪ Members are less than 13 years of age and CD-4 Count is > 200/mm3 • Neurological disorders: ○ Guillain-Barre' Syndrome ○ Relapsing-Remitting Multiple Sclerosis ○ Chronic Inflammatory Demyelinating Polyneuropathy ○ Myasthenia Gravis ○ Polymyositis and Dermatomyositis • Chronic Lymphocytic Leukemia (CLL) • Autoimmune Neutropenia (AN): ○ Absolute neutrophil count is less than 800 mm AND ○ Has recurrent bacterial infections • Autoimmune Hemolytic Anemia (AHA) • Liver or Intestinal Transplant • Idiopathic Thrombocytopenic Purpura (ITP): ○ Preoperatively for members undergoing elective splenectomy with platelet count < 20,000 ○ Members with active bleeding & platelet count <30,000. ○ Pregnant women with platelet counts <10,000 in the third trimester. ○ Pregnant women with platelet count 10,000 to 30,000 who are bleeding.	One year CLL: One year AN: 6 months AHA: 5 weeks ITP: 5 days
JADENU and EXJADE (Deferasirox)	**Jadenu®** and **Exjade®** will be approved for members that meet the following criteria: • Must be prescribed in conjunction with a hematologist or oncologist AND • Member's weight must be provided AND • Member has a diagnosis for chronic iron overload due to blood transfusion AND • Member is 2 years of age or older AND • Member has consistently high serum ferritin levels > 1000 mcg/L (demonstrated by at least 2 values in the prior three months OR • Member has a diagnosis for chronic iron overload due to non-transfusion dependent thalassemia syndromes AND • Member is 10 years of age or older AND • Member has liver iron levels > 5 mg iron per gram of dry weight and serum ferritin levels > 300 mcg/L document in the prior three months Members must also meet the following additional criteria for all Jadenu and Exjade approvals: • Member does not have advanced malignancies and/or high-risk myelodysplastic syndromes AND • Member has a creatinine clearance > 40 ml/min AND • Member has a platelet count > 50 x 10^9/L Maximum Dosing: Maximum dose of Jadenu® is 28mg/kg/day Maximum dose of Exjade® is 40mg/kg/day	One Year

KALYDECO (ivacaftor)	**Kalydeco®** will only be approved if all of the following criteria are met: • Member has been diagnosed with cystic fibrosis AND • Member is an adult or pediatric patient 2 years of age or older AND • Documentation has been provided to indicate one of the following gene mutation: in the CFTR gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, R117H, S549R or another FDA approved gene mutation.* AND • Documentation has been provided that baseline ALT and AST have been accessed and are within 2x normal limits (AST and ALT should be examined every 3 months for the first year and annually after that). * If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use. Kalydeco® will only be approved at doses no more than 150 mg twice daily. Prior Authorizations need to be obtained yearly. Kalydeco® will not be approved for members who are concurrently receiving rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's Wort.	One year
KUVAN (sapropterin dihydrochloride)	**Kuvan®** will be approved if all the following criteria are met: • Member is > 1 month old AND • Member has been diagnosed with hyperphenylalaninemia due to tetrahydrobiopterin responsive phenylketonuria AND • Prescriber is a metabolic specialist AND • Phenylalanine levels must be greater than 6 mg/dL for neonates through 12 years of age OR • Phenylalanine levels must be greater than 10 mg/dL for members between 13 to 17 OR • Phenylalanine levels must be greater than 15 mg/dL for members 18 years and older AND • Must be in conjunction with dietary restriction of phenylalanine • Initial approval will be for 1 month. Authorization may be extended if: o Members on the 10mg/kg/day dose whose blood phenylalanine levels have not decreased from baseline after 1 month of treatment should increase to 20mg/kg/day. These members will be approved for another 1 month trial at the higher dose. o Members on the 20mg/kg/day dose whose blood phenylalanine levels have not decreased from baseline after 1 month are considered non-responders, and treatment will be discontinued. o Members responding to therapy receive additional authorization at 1-year intervals.	Initial approval one month
LHRH/GnRH Luteinizing Hormone Releasing Hormone/Gonadotropin Releasing Hormone	Must be given in the member's home or in a long-term care facility. Prior authorization will be granted for FDA Approved Indications Only: • **Eligard®:** Palliative-treatment of Advanced Prostate Cancer • **Lupron®:** Prostate Cancer, Endometriosis, Uterine Leiomyomata (fibroids), Precocious Puberty Lupron® will be approved for Gender Identity Dysphoria based on the following criteria: o The member has a diagnosis of Gender Identity Dysphoria which is made by a mental health professional with experience in treating gender dysphoria.	One year

	Where available, the mental health professional should ideally have training in child and adolescent developmental psychology AND o The member should have at least 6 months of counseling and psychometric testing for gender identity prior to initiation of Lupron AND o The prescribing provider has training in puberty suppression using a gonadotropin releasing hormone agonist AND o Lupron may not be started until girls and boys exhibit physical changes of puberty (confirmed by levels of estradiol and testosterone, respectively) and no earlier than Tanner stages 2-3 (bilateral breast budding or doubling to tripling testicular size to 4-8 cc). o Duration of treatment: Lupron will be covered to a maximum of 16 years of age for Gender Identity Dysphoria. • **Trelstar®**: Palliative treatment of Advanced Prostate Cancer • **Viadur®:** Palliative treatment of Advanced Prostate Cancer • **Vantas®**: Palliative treatment of Advanced Prostate Cancer • **Zoladex®**: Breast Cancer, Endometriosis, Endometrial Thinning, Prostate Cancer	16 years of age
LIPIDS/AMINO ACIDS/PLASMA PROTEINS	Approval will be given if administered in the member's home or in a long-term care facility. If given in the hospital or physician's office, the claim must be billed as a medical expense.	Lifetime
MAKENA (hydroxyprogesterone caproate) vial and autoinjector	**Makena®** will be approved for members that meet the following criteria: • The drug is being administered in the home or in long-term care setting • Member has a Singleton pregnancy and a history of singleton spontaneous preterm birth • Therapy is being initiated between 16 weeks gestation and 20 weeks 6 days gestation and continued through 36 weeks 6 days gestation or delivery (whichever occurs first) • Dose is administered by a healthcare professional. <u>Maximum Dosing:</u> Makena vial: 250mg IM once weekly Makena autoinjector: 275mg SubQ once weekly	See criteria
MOXATAG (amoxicillin)	A prior authorization will only be approved if a member is allergic to inactive ingredients in immediate release amoxicillin.	One year
MYALEPT (metreleptin)	MYALEPT will be approved if all of the following criteria are met: • Prescriber is an endocrinologist who is enrolled in the Myalept REMS program AND • Member has a diagnosis of congenital or acquired generalized lipodystrophy AND • Member does not have HIV-related lipodystrophy AND • Member has a diagnosis of leptin deficiency AND • Member has been diagnosed with poorly controlled diabetes (HgA1c > 7) and/or hypertriglyceridemia (> 500 mg/dl) AND • Member has tried and failed two standard therapies for diabetes and/or hypertriglyceridemia	Six Months
NEWLY APPROVED PRODUCTS	Newly marketed drugs may be subject to prior authorization for a minimum of nine months following FDA marketing approval. Initial approval criteria will include non-preferred criteria (for drugs within a reviewed PDL class); or FDA approved indications, dose, age and place in therapy. For drugs in PDL classes, the next class annual review will include the new agent. For non-PDL drugs, criteria shall be reviewed at the quarterly DUR meeting closest to the nine month minimum.	One year
NORTHERA (droxidopa)	**Northera®** will be approved if all the following is met:	3 months

	• Member has a diagnosis of symptomatic neurogenic orthostatic hypotension (NOH) as defined by one of the following when an upright position is assumed or when using a head-up tilt table testing at an angle of at least 60 degrees. o At least a 20 mmHg fall is systolic pressure o At least a 10 mmHg fall in diastolic pressure AND • NOH caused by one of the following: o Primary autonomic failure (e.g, Parkinson's disease, multiple system atrophy, and pure autonomic failure o Dopamine beta-hydroxylase deficiency o Non-diabetic autonomic neuropathy AND • Member does not have orthostatic hypotension due to other causes (e.g, heart failure, fluid restriction, malignanacy) AND • Members has tried at least three of the following non-pharmacological interventions: o Discontinuation of drugs which can cause orthostatic hypotension [e.g., diuretics, antihypertensive medications (primarily sympathetic blockers), anti-anginal drugs (nitrates, excluding SL symptom treatment formulations), alpha-adrenergic antagonists, and antidepressants] o Raising the head of the bed 10 to 20 degrees o Compression stockings o Increased salt and water intake, if appropriate o Avoiding precipitating factors (e.g., overexertion in hot weather, arising too quickly from supine to sitting or standing) AND • NORTHERA is being prescribed by either a cardiologist, neurologist, or nephrologist AND • Member has failed a 30 day trail, has a contraindication, or intolerance to both Florinef (fludrocortisone) and ProAmatine (midodrine).	
NUCALA (mepolizumab)	A prior authorization will only be approved as a pharmacy benefit when the medication is administered in a long-term care facility. Medications administered in a physician's office must be billed as a medical expense. Because this medication has a Black Box warning requiring the administration under the supervision of a physician, a PA will not be approved if administered in a member's home.	One year
NUEDEXTA (dextromethorphan /quinidine)	**Nuedexta®** will be approved for members who meet the following criteria: • Nuedexta® is being prescribed for diagnosis of pseudobulbar affect caused by structural neurologic condition (i.e. MS or ALS) AND • Member has a Center for Neurologic Study-Lability Scale (CNS-LS) score of 13 or higher AND • Member has at least 10 episodes of inappropriate laughing or crying per day before therapy AND • Member has a baseline electrocardiogram (ECG) with no significant abnormalities and no history of QT prolongation syndrome AND • Nuedexta® is prescribed by a neurologist or in conjunction with a neurologist AND Member has trailed and failed one tricyclic antidepressant and one selective serotonin reuptake inhibitor within the past year (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) • Initial approval will be given for 3 months, continued approval for one year will be given if member has 50% reduction in daily episodes at 3 months of therapy	Initial Approval: 3 months Continuation Approval: One year

	• Max Dose: Nuedexta® (dextromethorphan 20mg/quinidine 10mg) 2 capsules per day (given every 12 hours) Renewal: members currently stabilized on this medication may continue to receive it with a documented diagnosis of pseudobulbar affect and evidence of efficacy (documentation of decrease in pseudobulbar episodes by 50% from baseline)	
OFEV (nintedanib)	**Ofev®** will be approved if all the following criteria are met: • Member has been diagnosed with idiopathic pulmonary fibrosis AND • Is being prescribed by or in conjunction with a pulmonologist AND • Member is 18 years or older AND • Member has baseline ALT, AST, and bilirubin prior to starting therapy AND • Member does not have moderate (Child Pugh B) or severe (Child Pugh C) hepatic impairment AND • Female members of reproductive potential must have been counseled regarding risk to the fetus and to avoid becoming pregnant while receiving treatment with Ofev and to use adequate contraception during treatment and at least 3 months after the last dose of Ofev AND • Member is not taking a P-gp or CYP3A4 inducer (e.g, rifampin, carbamazepine, phenytoin, St. John's Wort) Quantity Limits: 60 tablets/30 days	One year
OMEGA-3 ETHYL ESTERS	Omega-3-acid ethyl esters will be approved for members that have confirmed diagnosis of hypertriglyceridemia defined as TG ≥ 500 mg/dL	1 year
ONFI (clobazam)	**Onfi®** will be approved for members who meet the following criteria: • Member is ≥ 1 year of age and has a documented diagnosis of Dravet syndrome OR • Member is > 2 years of age AND • Has a documented diagnosis of seizure AND • Is being prescribed by or in conjunction with a neurologist AND • Has failed a one month trial with three anticonvulsants (Failure is defined as: lack of efficacy, allergy, intolerable side effects contraindication to, or significant drug-drug interactions).	1 year
OPIOID AGONIST/ANTAGONIST	**Revia (naltrexone)** - A PA is not required. **Naloxone vial or prefilled syringe –** a prior authorization is not required. The atomizer device for use with naloxone can be obtained by the pharmacy billing as a DME claim code A4210. The unit limit is 1 atomizer per vial/syringe dispensed up to a total of 15 per year. A prior authorization is not required. **Bunavail® (buprenorphine/naloxone)** buccal film will be approved for members who meet the following criteria: • Approval will be granted if the prescriber meets the qualification criteria under the Drug Addiction Treatment Act (DATA) of 2000 and has been issued a unique DEA identification number by the DEA, indicating that he or she is qualified under the DATA to prescribe Subutex® or Suboxone® AND • The member has a diagnosis of opioid dependence AND • The member is 16 years of age or older AND • No claims data show concomitant use of opiates in the preceding 30 days unless the physician attests the member is no longer using opioids AND • The member must have tried and failed, intolerant to, or has contraindication to generic buprenorphine/naloxone SL tablets or Suboxone films. **Evzio (naloxone)** is not currently a Medicaid benefit.	One year

	Narcan (naloxone) – A PA is not required. **Sublocade (buprenorphine extended-release)** will be approved for members who meet the following criteria: • SUBLOCADE is being administered in a long-term care facility or in a member's home by a home healthcare provider AND ◦ SUBLOCADE is being dispensed directly to the home healthcare professional (medication should not be dispensed directly to the member) • Provider attests to member's enrollment in a complete treatment program including counseling and psychosocial support AND • Member must have documented diagnosis of moderate to severe opioid use disorder AND • Member must have initiated therapy with a transmucosal buprenorphine-containing product, and had dose adjustment for a minimum of 7 days AND • Max dose: SUBLOCADE 300 mg injection every month **Suboxone (buprenorphine/naloxone)** will be approved if the following criteria are met: • The prescriber is authorized by the manufacturer to prescribe Suboxone • The member has an opioid dependency • The member is not currently receiving an opioid or opioid combination product unless the physician attests the member is no longer using opioids. • Will not be approved for the treatment of pain. • Opioid claims will not be allowed for members with a claim for Suboxone in the preceding 30 days. • will not be approved for more than 24mg of buprenorphine /day **Subutex (buprenorphine)** will be approved if all of the following criteria are met: • The prescriber is authorized by the manufacturer to prescribe Subutex • The member has an opioid dependency • The member is pregnant or the member is allergic to Naloxone • Subutex will not be approved for the treatment of pain. • Subutex will not be approved for more than 24mg/day **Vivitrol (naltrexone)** • Approval will be given if administered in the member's home or in a long-term care facility. If given in the hospital or physician's office, the claim must be billed as a medical expense. **Zubsolv (buprenorphine/naloxone)** • Approval will be granted if the prescriber meets the qualification criteria under the Drug Addiction Treatment Act (DATA) of 2000 and has been issued a unique DEA identification number by the DEA, indicating that he or she is qualified under the DATA to prescribe Subutex or Suboxone AND • The member has a diagnosis of opioid dependence AND • The member is 16 years of age or older AND • No claims data show concomitant use of opiates in the preceding 30 days unless the physician attests the member is no longer using opioids AND • The member must have tried and failed, intolerant to, or has a contraindication to generic buprenorphine/naloxone SL tablets or Suboxone films.	
ORKAMBI (lumacaftor/ivacaftor)	**Orkambi®** will be approved for members if the following criteria has been met:	One year

	• Member must have diagnosis of cystic fibrosis with genetic testing performed to confirm that member is homozygous for the F508del mutation in the CFTR gene AND • Member is 6 years of age or older AND • Member is being treated by a pulmonologist AND • Member has < 5 times upper limit of normal (ULN) AST/ALT or < 3 times ULN AST/ALT if concurrently has > 2 times ULN bilirubin at time of initiation AND • Member has serum transaminase and bilirubin measured before initiation and every 3 months during the first year of treatment	
OTC PRODUCTS*	OTC products covered without a prior authorization include: o Aspirin o OTC insulin o Oral emergency contraceptive products (i.e. Plan B) • L-methylfolate will be approved for members with depression who are currently taking an antidepressant and are partial or non-responders • Nicomide will be approved for the treatment of acne • Cranberry tablets will be approved for urinary tract infections • Cough and Cold Products will be approved for members with a diagnosis of a chronic respiratory condition for which these medications may be prescribed or based on medical necessity supported by clinical practice recommendations • Combination antihistamine/decongestant products will be approved for members with a diagnosis of seasonal or perennial allergic rhinitis or chronic sinusitis or based on medical necessity supported by clinical practice recommendations • Guaifenesin 600mg LA will be approved for members having an abnormal amount of sputum • The following iron-containing products changed from Rx-required to OTC status in response to an FDB prescription designation status change made on 06/07/2018. These products will continue to be covered as OTC products for members with a diagnosis of iron deficient anemia: Feriva 21-7, Ferralet 90, Ferraplus 90, Folcalgin DSS, Folivane-F, Fusion Plus, Hematogen Forte, Integra F, Integra Plus, Irospan 24/6, Trigels-F Forte. • Diabetic needles and supplies are covered under the DME benefit • Quinine sulfate *is no longer covered* for leg cramps • Broncho saline: *See Sodium Chloride section* • Fluoride supplements: *See Fluoride Products section* • OTC Proton Pump Inhibitors: *See PDL Proton Pump Inhibitor section* • Long Term Care Facilities (LTCFs): Various OTC drugs and supplies for LTCF residents shall be furnished by the facility, within the per diem rate, at no charge to the resident pursuant to 10 CCR 2505-10 Skilled Nursing Facility: 8.440 NURSING FACILITY BENEFITS. These OTC drugs and supplies, known as products on a "floor stock list", are not covered or eligible for prior authorization under the pharmacy benefit for LTCF members. *Members with Erythema Bullosum (EB) can receive any OTC medication with a prior authorization.	One year
OTREXUP (methotrexate)	**Otrexup®** authorization will be approved for members who meet the following criteria: • Member has diagnosis for rheumatoid arthritis AND • Member cannot take methotrexate by mouth due to intolerable gastrointestinal side effects AND • Member cannot administer generic methotrexate by injection due to limited functional ability.	One year

<table>
<tr><td>OXSORALEN
(methoxsalen)</td><td>Approval will be granted with diagnosis of: Myosis; Fungoides; Psoriasis or Vitiligo</td><td>One year</td></tr>
<tr><td>PCSK9 INHIBITORS
Praluent, Repatha</td><td>PCSK9 injections will be approved for members that meet the following criteria:
• Member has the below diagnosis for each agent below:
o Praluent®: heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease
o Repatha®: heterozygous familial hypercholesterolemia or homozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease AND
<table><tr><td>Conditions Which Define Clinical Atherosclerotic Cardiovascular Disease</td></tr><tr><td>• Acute Coronary Syndrome
• History of Myocardial Infarction
• Stable or Unstable Angina
• Coronary or other Arterial Revascularization
• Stroke
• Transient Ischemic Attach
• Peripheral Arterial Disease of Atherosclerotic Origin</td></tr></table>• PCSK9 is prescribed by, or in consultation with, one of the following providers: AND
o Cardiologist
o Lipid Specialist
o Endocrinologist AND
• Member is concurrently adherent (>80% of the past 90 days) on maximum doses (see table below) of statin therapy (must include atorvastatin and rosuvastatin). If member is intolerant to statins due to side effects, must have documented three-month trial and failure of pravastatin and one other statin at lower doses and/or every other day treatment. For members with a past or current incidence of rhabdomyolysis, three-month failure is <u>not</u> required AND
<table><tr><td>Atorvastatin 80mg</td></tr><tr><td>Fluvastatin 80 mg</td></tr><tr><td>Lovastatin 80 mg</td></tr><tr><td>Pravastatin 80 mg</td></tr><tr><td>Rosuvastatin 40 mg</td></tr><tr><td>Simvastatin 40 mg (80 mg not used in practice)</td></tr></table>• The member has <u>not</u> achieved 50% reduction in LDL-C from baseline while > 80% adherent for the past 180 days on maximally tolerated statin, diet and adjunct lipid lowering therapies AND
• Prescribing provider attests to providing appropriate counseling regarding lipid-lowering diet AND
• Member must be concurrently treated (in addition to statin) with one of the following unless contraindicated or significant safety concern exists: ezetimibe or bile acid sequestrant AND
• LDL-C levels must be ≥ 190 AND
• PA will be granted for 12 weeks initially, and LDL-C will be required after 8 weeks of treatment for dose optimization. A reduction in LDL-C of at least 45 % since initiation of treatment with PCSK9 is required to continue therapy.</td><td>Initial Approval: 12 weeks

Continuation Approval: One year</td></tr>
</table>

PHYSICIAN ADMINISTERED DRUGS	Medications given in a hospital, doctor's office or dialysis unit are only to be billed directly by those facilities as a medical item. IV Fluids, meds, etc. may be billed by the pharmacy when given in a long-term care facility or by home infusion following prior authorization approval. Prior authorizations will be approved based upon documentation of the location for administration.	

PREVYMIS (letermovir)	**Prevymis®** will be approved for members that meet the following criteria:
	• Member is a CMV-seropositive transplant recipient and meets ALL of the following: AND
	  o Member is 18 years or older.
	  o Member has received an allogeneic hematopoietic stem cell transplant.
	  o Member does not have severe hepatic impairment (Child-Pugh Class C).
	  o Member is not receiving pitavastatin or simvastatin co-administered with cyclosporine.
	  o Member is not receiving pimozide or ergot alkaloids.
	• Prevymis® is being prescribed by or in consultation with an oncologist, hematologist, infectious disease specialist, or transplant specialist. AND
	• Provider agrees to monitor for CMV reactivation. AND
	• Prevymis® dose does not exceed 480 mg orally or dose does not exceed 240mg if co-administered with cyclosporine. AND
	• If request is for IV injectable Prevymis®, must provide medical justification why the patient cannot use oral therapy. AND
	• If request is for IV injectable Prevymis®, must be administered in a long-term care facility or in a member's home by a home healthcare provider
	
	Length of Approval: Prevymis® will only be approved for 100 days
	
	Renewal: Authorization may be reviewed every 100 days to confirm that current medical necessity criteria are met and that the medication is effective (e.g. no evidence of CMV viremia).
		100 days

PROCYSBI (cysteamine)	Approval will be granted if the member is 2 years of age or older **AND** Has a diagnosis of nephropathic cystinosis **AND** documentation is provided to the Department that treatment with cysteamine IR (Cystagon®) was ineffective, not tolerated, or is contraindicated.	One year

PROMACTA (eltrombopag)	**Promacta®** prior authorization will be approved for members meeting criteria for the following diagnoses:
	
	<u>Chronic immune idiopathic thrombocytopenia purpura:</u>
	• Confirmed diagnosis of chronic (> 3 months) immune idiopathic thrombocytopenia purpura AND
	• Must be prescribed by a hematologist AND
	• Member is at risk (documented) of spontaneous bleed as demonstrated by the following labs: AND
	  o Platelet count less than 20,000/mm3 or
	  o Platelet count less than 30,000/mm3 accompanied by signs and symptoms of bleeding
	• In the past 6 months, member has tried and failed (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) systemic corticosteroids (e.g. prednisone 1 to 2 mg/kg for 2 to 4 weeks, or pulse dexamethasone 40 mg daily for 4 days), immunoglobulin replacement, or splenectomy.
	
	<u>Thrombocytopenia associated with hepatitis C:</u>
		One year*

	• Member must have confirmed diagnosis of chronic hepatitis C associated thrombocytopenia AND • Must be prescribed by a gastroenterologist, infectious disease specialist, transplant specialist or hematologist AND • Member has clinically documented thrombocytopenia defined as platelets < 60,000 microL AND • Patients' degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy <u>Severe aplastic anemia:</u> • Member must have confirmed diagnosis of Severe Aplastic Anemia AND • Must be prescribed by a hematologist AND • Member must have had a documented insufficient response to immunosuppressive therapy (antithymocyte globulin (ATG) alone or in combination with cyclosporine and/or a corticosteroid *All initial prior authorization approvals will be granted for 12 months. Further approvals for a maximum of 6 months require lab results and documentation for efficacy.	
PROMETHAZINE	A Prior authorization is required for all routes of administration for members under the age of two. Children under the age of two should not use Promethazine. Promethazine is contraindicated in such patients because of the potential for fatal respiratory depression. Not qualified for emergency 3 day supply PA	One year
PROPECIA (finasteride)	***Not covered for hair loss*** *Not qualified for emergency 3 day supply PA*	One year
PULMOZYME (dornase alfa)	**Pulmozyme®** will be approved for members that meet the following criteria: • Member has a diagnosis of cystic fibrosis AND • Member is five years of age or older o For children < 5 years of age, Pulmozyme will be approved if the member has severe lung disease as documented by bronchoscopy or CT scan Pulmozyme twice daily will only be approved if patient has tried and failed an adequate trial of once daily dosing for one month All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon documentation from the prescriber that the member continues to benefit from Pulmozyme therapy. Quantity Limits: 30 ampules (2.5 mg/2.5 ml) per month	
RADICAVA (edaravone)	**Radicava®** will be approved for members that meet the following criteria: • RADICAVA is being administered in a long-term care facility or in a member's home by a home healthcare provider AND • Member has a "definite" or "probable" diagnosis of amyotrophic lateral sclerosis (ALS) based on medical history and diagnostic testing which may include imaging and nerve conduction conditions studies AND	6 months

	• Member meets ALL of the following:
	  o Member has a diagnosis of ALS for 2 or less years (for new starts only).
	  o Diagnosis has been established by or with the assistance of a neurologist with expertise in ALS using El Escorial or Airlie House diagnostic criteria (ALSFRS-R).
	  o Member has normal respiratory function as defined as having a percent-predicated forced vital capacity of greater than or equal to 80%.
	  o The ALSFRS-R score is greater than or equal to 2 for all items in the criteria.
	  o Member does not have severe renal impairment (CrCl< 30 ml/min) or end stage renal disease
	  o Member does not have moderate or severe hepatic impairment (Child-Pugh Class C) AND
	• RADICAVA is prescribed by or in consultation with a neurologist.
	
	Length of Approval: 6 months.
	Quantity Limits: For patients initiating therapy, approval will include 28 bags per 28 days (initial dose) for the first month and 20 bags per 28 days for the remainder of the 6 months.
	Renewal: Authorization may be reviewed every six months to confirm that current medical necessity criteria are met and that the medication is effective per improvement in ALSFRS-R score.	

RASUVO (methotrexate)	**Rasuvo®** will be approved for members who meet the following criteria: • Member has diagnosis for rheumatoid arthritis AND • Member cannot take methotrexate by mouth due to intolerable gastrointestinal side effects AND • Member cannot take a methotrexate injection via syringe due to limited functional ability	One year
RAVICTI (glycerol phenylbutyrate)	**Ravicti®** will only be approved for members meeting the following criteria: • Member must be 2 years of age or older • Member must have a documented diagnosis of urea cycle disorder (UCD) • Member must be on a dietary protein restriction (verified by supporting documentation) • Member must have tried and failed Buphenyl as evidenced by uncontrolled hyperammonia over the past 365 days • Medication must be prescribed by a physician experienced in the management of UCD (e.g., geneticist)	One year
REBATE DISPUTE DRUGS	Medical necessity. Not qualified for emergency 3 day supply PA	One year
REQUIP XL (pramipexole)	A prior authorization will only be approved if a member has tried and failed on generic immediate release ropinirole for a period of 3 or more months in the last 6 months and the member has a diagnosis of Parkinson's disease. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) **Grandfathering:** Members who have been previously stabilized on Requip XL can receive approval to continue on the medication for one year if medically necessary.	One year
SANDOSTATIN (octreotide)	Approved for: acromegaly; carcinoid tumors; and vasoactive intestinal peptide tumors.	Lifetime

SILENOR (doxepin)	A prior authorization will be approved if a member meets one of the following criteria: • Contraindication to preferred oral sedative hypnotics (Lunesta, zaleplon and zolpidem) • Medical necessity for doxepin dose < 10 mg • Age greater than 65 years old or hepatic impairment (3 mg dose will be approved if these criteria is met)	One year
SIMVASTATIN 80mg	Simvastatin 80mg dose products will only be covered for members who have been stable for more than 12 months at that dose. Providers should consider alternate preferred statins in members who have not met cholesterol goals on simvastatin at doses up to 40mg per day. Please refer to the FDA communication entitled, "FDA Drug Safety Communication: New restrictions, contraindications, and dose limitations for Zocor (simvastatin) to reduce the risk of muscle injury" for updated guidance on contraindications, dose limits and relative LDL lowering doses of alternatives.	One year
SODIUM CHLORIDE (inhalation)	Broncho Saline is **not** covered as a drug benefit. Inhaled NaCl is now classified as a supply and can only be billed as medical. All requests for sodium chloride (inhalation use) must be billed through medical.	N/A
SOLARAZE 3% GEL (diclofenac sodium)	A prior authorization will only be approved if the member has a diagnosis of Actinic Keratoses (AK).	One year
STRENSIQ (asfotase alfa)	**Strensiq®** will be approved if all the following is met: Member has a diagnosis of either perinatal/infantile- OR juvenile-onset hypophosphatasia (HPP) based on all of the following a. Member was ≤ 18 years of age at onset b. Member has/had clinical manifestations consistent with hypophosphatasia at the age of onset prior to age 18 (e.g. vitamin B6-dependent seizures, skeletal abnormalities: such as rachitic chest deformity leading to respiratory problems or bowed arms/legs, "failure to thrive"). c. Member has/had radiographic imaging to support the diagnosis of hypophosphatasia at the age of onset prior to age 18 (e.g. infantile rickets, alveolar bone loss, craniosynostosis) d. Member has one of the following: elevated urine concentration of phosphoethanolamine (PEA), elevated serum concentration of pyridoxal 5'-phosphate (PLP) in the absence of vitamin supplements within one week prior to the test, or elevated urinary inorganic pyrophosphate (PPi) AND e. Molecular genetic test has been completed confirming mutations in the ALPL gene that encodes the tissue nonspecific isoenzyme of ALP (TNSALP) within 30 days of initiation. If genetic test is negative, approval will not be granted past 30 days. f. Prescriber is a specialist in the area of the members disease (e.g, endocrinologist)	Six Months
SYMDEKO (tezacaftor/ivacaftor and ivacaftor)	**Symdeko®** will be approved for members that meet the following criteria: • The member has a diagnosis of cystic fibrosis AND • The member is 12 years of age or older AND • The member has one of the following mutations: o Homozygous for the F508del mutation in the CFTR gene 2 OR o Heterozygous for the F508del mutation in the CFTR gene and one of the following mutations: E56K, P67L, R74W, D110E, D110H, R117C, E193K, L206W, R347H, R352Q, A455E, D1270N, D579G, 711+3A-G, E831X, S945L, S977F, F1052V, K1060T,	One year

	A1067T, R1070W, F1074L, D1152H, 3272-26A-G, 2789+5G-A, 3849-10kbC-T AND • Member has ALT, AST, and bilirubin at baseline and tested every 3 months for the first year AND • Member has a baseline ophthalmological examination and periodic follow-up exams for cataracts AND • Must be prescribed by or in consultation with a pulmonologist or gastroenterologist AND • Member is not receiving dual therapy with another cystic fibrosis transmembrane conductance regulator (CFTR) potentiator AND • Member has had 2 negative respiratory cultures for any of the following organisms: *Burkholeria cenocepacia*, *Burkholderia dolosa*, or *Mycobacterium abscessus* in the past 12 months.	
SYNAGIS (palivizumab)	**Pharmacy Prior Authorization requests for Synagis® must be submitted by fax or phone using the Synagis® Prior Authorization Form found at** https://www.colorado.gov/hcpf/provider-forms. **Medical PAs must be submitted through eQHealth at** http://coloradopar.com/. **Synagis® season will begin November 27, 2017 and end April 30, 2018. PARs may be requested beginning November 16, 2017.** **Key Points** 1. No more than 5 doses per season. 5 doses provide more than 6 months of protective serum concentration. 2. Synagis® is not recommended for controlling outbreaks of health care-associated disease. 3. Synagis® is not recommend for prevention of health care-associated RSV disease. 4. Infants born later in the season may require less than 5 doses to complete therapy to the end of the season. 5. Monthly prophylaxis should be discontinued in any child who experiences a breakthrough RSV hospitalization. 6. Synagis® is not recommended to prevent wheezing, nosocomial disease, or treatment of RSV 7. Synagis® is not routinely recommended for patients with a diagnosis of Down syndrome unless they also have a qualifying indication listed below. 8. In the **first year of life** Synagis® is recommended: a. For infants born before 29w 0d gestation. b. For infants born before 32w 0d **AND** with CLD of prematurity **AND** requirements of >21% oxygen for at least 28 days after birth. c. For infants with hemodynamically significant heart disease (acyanotic heart disease who are receiving medication to control CHF and will require cardiac surgical procedures **AND** infants with moderate to severe pulmonary hypertension**) AND** born within 12 months of onset of the RSV season. d. Children who undergo cardiac transplantation during the RSV season. e. For infants with cyanotic heart defects AND in consultation with a pediatric cardiologist AND requirements of >21% oxygen for at least 28 days after birth AND continue to require medical intervention (supplemental oxygen, chronic corticosteroid, or diuretic therapy) f. If an infant has neuromuscular disease or pulmonary abnormality AND is unable to clear secretions from the upper airways g. A child who will be profoundly immunocompromised during the RSV season (solid organ or hematopoietic stem cell transplantation, receiving chemotherapy)	Maximum of 5 doses per season

	h. An infant with cystic fibrosis with clinical evidence of CLD AND/OR nutritional compromise 9. In the **second year of life** Synagis® is recommended for: a. Infants born before 32w 0d **AND** with CLD of prematurity **AND** requirements of >21% oxygen for at least 28 days after birth **AND** continue to require medical intervention (supplemental oxygen, chronic corticosteroid, or diuretic therapy) b. A child who will be profoundly immunocompromised during the RSV season (solid organ or hematopoietic stem cell transplantation, receiving chemotherapy) c. Infants with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities of chest radiography or chest computed tomography that persist when stable) **OR** weight for length less than the 10th percentile. d. Children who undergo cardiac transplantation during the RSV season.	
SYPRINE (trientine)	Prior Authorization required and will be approved on a case by case basis The Drug Utilization Review (DUR) will be reviewing criteria	
TARGETED IMMUNE MODULATORS (IV products)	Entyvio (vedolizumab): • Entyvio will be approved for adult members with ulcerative colitis or Crohn's Disease AND • For Diagnosis of Crohn's Disease, have trialed and failed Humira and Cimzia OR • For Diagnosis of Ulcerative Colitis, have trialed and failed Humira and Simponi AND o Failure is defined as (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) • Has had an inadequate response with, intolerance to, or demonstrated a dependence on corticosteroids AND • Will be receiving Entyvio in a home health or long-term care setting AND • Member is not receiving Entyvio in combination with Humira, Simponi, or Tysabri AND • Entyvio Is initiated and titrated per FDA labeled dosing for Crohn's Disease and Ulcerative Colitis up to a maximum of 300mg IV infusion every 8 weeks Orencia (abatacept) – will be approved for members who are receiving the infusion in their home or in long-term care and who meet one of the following: • Members with moderate to severe rheumatoid arthritis who have failed therapy with both Enbrel and Humira • Members with moderate to severe juvenile idiopathic arthritis Remicade (infliximab) will be approved for members who are receiving the infusion in their home or in long-term care and who meet one of the following: • members with ulcerative colitis • members with rheumatoid arthritis who have tried and failed therapy with both Enbrel and Humira • members with psoriatic arthritis • members with ankylosing spondylitis • members with juvenile idiopathic arthritis • members with plaque psoriasis • members with Crohn's Disease Rituxan (rituximab) IV and subcutaneous - will be approved for administration in a long-term care facility or in a member's home by a home healthcare provider AND for members who meet one of the following:	One year

<table>
<tr><td></td><td>• Members with moderate to severe rheumatoid arthritis who have tried and failed both Enbrel and Humira
• Members with Chronic Lymphocytic Leukemia
• Members with Non-Hodgkins Lymphoma

Prior Authorizations for biosimilars Inflectra and Renflexis may be approved on a case by case basis.</td><td></td></tr>
<tr><td>THROMBOLYTIC ENZYMES</td><td>Approved for IV Catheter Clearance or Occluded AV Cannula if given in member’s home or long term care facility.</td><td>One year</td></tr>
<tr><td>TOBACCO CESSATION (Prescription & OTC)</td><td>Prior authorization is required for all tobacco cessation medications except for the first fill of the gum/lozenge form of short-acting nicotine replacement therapy (NRT).

Members can receive combination therapy with patch form of long-acting NRT and gum/lozenge short-acting NRT per 90 day benefit.

Members should be referred to the QuitLine or another behavior modification program. The name of that program should be included on the prior authorization form.

Medical Assistance Program will pay for multiple strengths of a product (patch, gum, or lozenge) or multiple products during the two 90-day paid benefit periods.</td><td>Two 90-day paid benefits per year

Not qualified for emergency 3 day supply PA</td></tr>
<tr><td>TPN PRODUCTS</td><td>Approval will be given if administered in the member’s home or in a long-term care facility by a home healthcare provider. If given in the hospital or physician’s office, the claim must be billed as a medical expense.</td><td>Lifetime</td></tr>
<tr><td>TYBOST (cobicistat)</td><td>Tybost® will be approved for members who meet the following criteria:
• Member has a diagnosis of HIV-1 AND
• Member is currently being treated with atazanavir or darunavir only AND
• Member is not taking cobicistat-containing drugs, or ritonavir-containing drugs AND
• Member has failed treatment with ritonavir (failure defined as intolerable side effect, allergy, or lack of efficacy).</td><td>One year</td></tr>
<tr><td>VACCINES</td><td>All other vaccines must be bill on Colorado 1500 form as a medical expense unless administered in long-term care facility. Any vaccine can be approved by prior authorization if a member is living in a long-term care facility. (Not a covered benefit for regular patients – only long-term care facilities).

Not qualified for emergency 3 day supply PA</td><td>One year</td></tr>
<tr><td>VALCYTE (valganciclovir hydrochloride)</td><td>Valcyte® will be approved for members with diagnosis of Cytomegalovirus (CMV) retinitis AND acquired immunodeficiency Syndrome (AIDS) per dosing guidelines below
OR
For members that require prophylactic treatment for CMV post kidney, heart or kidney-pancreas transplant per dosing guidelines below
OR
For members ≤ 16 years of age that are at high risk of CMV infection and need prophylactic treatment post heart or kidney transplant per dosing guidelines below

<table><tr><td colspan="2">Adult Dosage</td></tr><tr><td>Treatment of CMV retinitis</td><td>Induction: 900 mg (two 250 mg tablets) twice a day for 21 days</td></tr></table></td><td>One year</td></tr>
</table>

	Maintenance: 900 mg once a day	
Prevention of CMV disease in heart or kidney-pancreas patients	900 mg once a day within 10 days of transplantation 100 days post-transplantation	
Prevention of CMV disease in kidney transplant patients	900 mg once a day within 10 days of transplantation until 200 days post-transplantation	
Pediatric Dosage		
Prevention of CMV disease in kidney transplant patients 4 month to 16 years of age	Dose once daily within 10 days of transplantation until 200 days post-transplantation	
Prevention of CMV disease in heart transplant patients 1 month to 16 years of age	Dose once a day within 10 days of transplantation until 100 days post-transplantation	
VELTASSA (patiromer)	**Veltassa®** prior authorization will be approved for members that meet the following criteria: • Documented diagnosis of hyperkalemia (serum potassium > 5 mEq/L) AND • Veltassa is not being used for emergent hyperkalemia AND • Member does not have severe gastrointestinal motility dysfunction AND • Member does not have hypomagnesemia (serum magnesium < 1.4 mg/dL)	One year
VERIPRED (prednisolone)	A prior authorization will only be approved if a member has tried and failed on a generic prednisolone product (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions.)	One year
VERSED (midazolam) Injection	Approved if given in the member's home or in a long-term care facility and given for: • Preoperative sedation or anesthesia • Terminally ill members with Cancer • Member with Erythema Bullosum (EB) –approval for one year	One month
VERSED (midazolam) Injectable Product for Intranasal Use	Midazolam injection used as for nasal inhalation will be approved for members who meet the following criteria: • Member is ≥ 6 months of age AND • Has a diagnosis of seizure disorder AND • Is prescribed by or in conjunction with a Neurologist AND • Treatment dose does not exceed 10mg Dosing Limits: 10 vials or prefilled syringes/month Only MIDAZOLAM 5mg/ml (for doses ≤ 5mg) and 10mg/2ml (for doses > 5 mg) will be covered. The atomizer device for use with midazolam can be obtained by the pharmacy billing as a DME claim code A4210. The atomizer dispensed limit is up to a total of 15 per year. A prior authorization is not required.	One year
VITAMINS (prescription vitamin products)	The following prescription vitamin products will be covered without prior authorization: • Vitamin D • Vitamin K • Prenatal vitamins prescribed for female members (prenatal vitamins are not covered for male members) *General prescription vitamin criteria (non-prenatal products): Prescription vitamin products will be approved for: • ESRD, CRF, renal insufficiency, diabetic neuropathy or renal transplant OR	One year

	• Members under the age of 21 with a disease state or clinical diagnosis associated with prohibited nutritional absorption processes as a secondary effect OR • Members with Erythema Bullosum Hydroxocobalamin injection will be approved for: • Members meeting any general prescription vitamin criteria* OR • Methylmalonic acidemia (MMA) Cyanocobalamin injections will be approved for: • Members meeting any general prescription vitamin criteria* OR • Vitamin B12 deficiency Folic acid prescription products will be approved for: • Members meeting any general prescription vitamin criteria* OR • Folic acid 1mg will be approved for female members without a prior authorization OR • Members currently taking methotrexate or pemetrexed OR • Documented folic acid deficiency by the treating clinician (megaloblastic and macrocytic anemia are the most common. Some drugs or other conditions may cause deficiency as well) OR • Homocysteinemia OR • Sickle cell disease OR • Female members prescribed folic acid for the prevention of a neural tube defect during pregnancy or for the prevention of miscarriage Cyanocobalamin/folic acid/pyridoxine prescription products will be approved for: • Members meeting any general prescription vitamin criteria* OR • Members with Homocysteinemia or Homocystinuria OR • Members on dialysis OR • Members with (or at risk for) cardiovascular disease Metanx will be approved for members with non-healing diabetic wounds	
VUSION OINTMENT (miconazole/zinc oxide/white petrolatum)	A prior authorization will only be approved if a member has failed on an OTC antifungal **and** a generic prescription antifungal. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)	One year
XIFAXAN (rifaximin)	**Xifaxan®** prior authorization will be approved for members meeting the following criteria: • For members prescribed Xifaxan for prophylaxis of hepatic encephalopathy (HE) in adults: o Member must be concomitantly taking lactulose or other non-absorbable disaccharide AND o Member must not have undergone transjugular intrahepatic portosystemic shunt (TIPS) procedure AND o Xifaxan is being prescribed for secondary prophylaxis of HE (member has experienced previous episode of HE) AND o Maximum dosing regimen is 550mg twice daily o Members meeting criteria will receive approval for one year • For members prescribed Xifaxan for irritable bowel syndrome with diarrhea (IBS-D): o Maximum dosing regimen is 550mg three times daily for 14 days AND	See Criteria

	○ Approval is limited to two 14-day treatment courses per 14 week time period • For members prescribed Xifaxan for traveler's diarrhea: ○ Member must be ≥ 12 years of age AND ○ Maximum dosing regimen is 200mg three times daily for 3 days ○ Members meeting criteria will receive approval for one year	
XOLAIR (omalizumab)	A prior authorization will only be approved as a pharmacy benefit when the medication is administered in a long-term care facility. Medications administered in a physician's office must be billed as a medical expense. Because this medication has a FDA Boxed Warning requiring administration under the supervision of a physician, a PA will not be approved if administered in a member's home.	One year
XYREM (sodium oxybate)	**Xyrem®** may be approved for adults if all the following criteria are met: • Member has a diagnosis of narcolepsy with excessive daytime sleepiness or cataplexy AND • Member must not have recent (within 1 year) history of substance abuse AND • Member is not taking opioids, benzodiazepines, alcohol, or sedative hypnotics (zolpidem, zaleplon, eszopiclone, chloral hydrate) concomitantly with Xyrem® AND • Member has a history of failure, contraindication, or intolerance for sleep induction/maintenance including zolpidem, zaleplon, eszopiclone, and temazepam AND • Member has trialed preferred psychostimulants for narcolepsy including Adderall, methylphenidate, and dexmethylphenidate AND • Prescriber is enrolled in Xyrem® REMS program • Maximum dose 9g/day	One year
YOSPRALA (aspirin/omeprazole)	**Yosprala®** will be approved for members who meet the following criteria: • Member requires aspirin for secondary prevention of cardiovascular or cerebrovascular events **AND** • Member is at risk of developing aspirin associated gastric ulcers (member is ≥ 55 years of age or has documented history of gastric ulcers) **AND** • Member has failed treatment with three preferred proton pump inhibitors in the last 6 months (Failure is defined as: lack of efficacy of a seven-day trial, allergy, intolerable side effects, or significant drug-drug interaction.)	One year